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| 10/574,084 | 05/15/2007 | Elisabeth Bock | BOCK9 | 3782 |

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| EXAMINER | |
|---|---|
| NOAKES, SUZANNE MARIE | |

| ART UNIT | PAPER NUMBER |
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| 1656 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/574,084 | BOCK ET AL. | |
| | Examiner | Art Unit | |
| | SUZANNE M. NOAKES | 1656 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11,28,30-39 and 41-65* is/are pending in the application.

4a) Of the above claim(s) *1-7,30-39,42 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,13,14,16,17,41,44-49 and 60-65* is/are rejected.

7)☒ Claim(s) *9,10,12,15,18-28 and 50-59* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Claims*

1. Claims 1-10, 12-28, 30-39 and 41-65 are pending. Claims 1-7, 30-39, 42 and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Thus, claims 8-10, 12-28, 41 and 44-65 are subject to examination.

### *Withdrawal of Previous Objections/Rejections*

2. Any rejection or objection recited in the previous Office action and not explicitly recited below is hereby withdrawn in view of Applicants amendments to the claims.

3. The objection to the Specification for lacking Sequence Compliance for Table 2 is withdrawn in view of the amendments to said table heading.

4. The previous objection to claim 8-28 and 41 withdrawn in view of the inclusion of the full meaning of the acronym NCAM in claim 8.

5. The rejection of claim 8, part (v) for lacking antecedent basis is withdrawn in view of the amendments to the claims.

***6.*** The rejection of claims 8 and 41 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendments to the claims which limits the claims to the peptides in parts I(a)-(d) and II. It is noted, however, that a new written description rejection has been necessitated by the amendments.

7.

***New Rejections/Objections – NOT Necessitated by Amendments***

***Claim Rejections - 35 USC § 112 – 2nd paragraph***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims13, 14, 16 and 17 are rejected for lacking antecedent basis. All claims are dependent upon claim 8, however, the sequences recited, e.g. SEQ ID Nos: 5, 6, 8 and 9, respectively are not recited anywhere in the independent claims.

***New Rejections/Objections –Necessitated by Amendments***

***Claim Objections***

10. Claim 44 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from multiple claims, wherein one of the claims is a withdrawn claim. See MPEP § 608.01(n). Accordingly, claim 44 has not been further treated on the merits.

***Claim Rejections - 35 USC § 112 – 1st paragraph***

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 8, 41, 44-49 and 60-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to any compound, natural or non-natural which is capable of binding to the nuclear cell adhesion molecule (NCAM) homolyphic binding site which is composed of the Ig1, Ig2 and Ig3 molecules. Parts i-iv of claim 8 suggest that the compound can bind between the Ig1 and Ig3 molecules by binding somewhere on Ig1 (i); or somewhere on Ig3 (ii); or bind somewhere on Ig2 which would disrupt to the Ig2-Ig3 interaction (iii) or bind somewhere on Ig3 to disrupt the Ig2-Ig3 interaction (iv), (v) binding to the Ig2 module of NCAM at said NCAM hemolyphic site wherein said compound is (I – (a) a peptide of SEQ ID NO: 1-4, 7, 10-14, 16, 17, 18, 40 or 41; (b) a peptide of I(a) which is fragment of that consists of at least 5 amino acids; (c) a peptide consisting of the peptide of I(a) with up to an additional 10 amino acids or (d) the peptide of I(a) (b) or (c) which differs soley by one or more amino acid substitutions but comprises at least a five amino acid fragment of a peptide of (a) ***or comprises*** *a sequence at least 50% identical to peptide of (a).*

Thus, part I(d) or claim 8 results in a huge genus of peptides which *comprise* the peptides of SEQ ID NO: 1, 2, 4, 7, 10-14, 16, 17, 18, 40 or 41 but need only have 50% identity to any of said peptides. Thus, the claim is drawn to a huge genus of polypeptides and peptides which does not require a common structure but rather a

common function as recited in parts (i)-(v) of claim 8. Furthermore, the claim is also drawn to a huge genus of these peptides wherein the specification only describes those species of ID NO: 1, 2, 4, 7, 10-14, 16, 17, 18, 40 or 41. These are not considered representative species in terms of structure and function of the very diverse and large genus.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

While the specification describes how to find various compounds which fit into the large and variable genus of compounds being claimed by performing *in vitro* assays (see for example pp. 26-29) or of utilizing the protein crystal or crystal structure of the Ig1-2-3 complex to perform *in silico* analysis (see for example, pp. 29-45 and 45-50), it is noted that this insufficient to claim the instant genus. The courts have established that possession, in terms of written description, may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. *See Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895.

Analogously, one cannot describe all chemical compounds, natural or not, based upon a pharmacophore (e.g. three-dimensional constraints of space such as those imposed by the Ig1-2-3 complex) wherein the compound is not required to have even a single common structural feature among the members of the species.

Thus, it is asserted that Applicant's are claiming a generic class of molecules, which is a huge genus essentially of unrelated molecules that do not have a structure function correlation, rather just a defined function. Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the broad scope of the genus as claimed.

***Maintained Rejections***

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 8, 41, 44-49 and 60-65 are rejected under 35 U.S.C. 102(b) as being anticipated by NCBI Accession polypeptide as first submitted by Small et al. (J. Cell Biol. 105:2335-2345 (1987) and identified as P13596.

The rejection was recited in the previous Office action but is reiterated below for convenience.

Small et al. teach the identification of the full length NCAM polypeptide from rat. Said sequence is 100% identical to the instant SEQ ID NOs: 1, 2, 4-6, 8, 9 and 11-26.

It is noted that the limitations of the indicated claims and the recitation of "having" is interpreted as being open comprising language. Thus, said polypeptide as taught by Small et al./NCBI Accession P13596 is asserted to inherently be capable of binding to the NCAM homolyphic binding site composed of Ig1-2-3.

**SEQ ID NO: 1 (P13596 – Small et al. – numbering reflects P13596)**

```
RESULT 2
NCAM1_RAT
ID   NCAM1_RAT                Reviewed;         858 AA.
AC   P13596;
DT   01-JAN-1990, integrated into UniProtKB/Swiss-Prot.
DT   01-JAN-1990, sequence version 1.
DT   25-NOV-2008, entry version 91.
DE   RecName: Full=Neural cell adhesion molecule 1;
DE            Short=NCAM-1;
DE            Short=N-CAM-1;
DE   AltName: CD_antigen=CD56;
DE   Flags: Precursor;
GN   Name=Ncam1; Synonyms=Ncam;
OS   Rattus norvegicus (Rat).
OC   Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC   Mammalia; Eutheria; Euarchontoglires; Glires; Rodentia; Sciurognathi;
OC   Muroidea; Muridae; Murinae; Rattus.
OX   NCBI_TaxID=10116;
RN   [1]
RP   NUCLEOTIDE SEQUENCE [MRNA].
RC   TISSUE=Brain;
RX   MEDLINE=88059265; PubMed=3680385; DOI=10.1083/jcb.105.5.2335;
RA   Small S.J., Shull G.E., Santoni M.-J., Akeson R.;
RT   "Identification of a cDNA clone that contains the complete coding
RT   sequence for a 140-kD rat NCAM polypeptide.";
RL   J. Cell Biol. 105:2335-2345(1987).
RN   [2]
RP   NUCLEOTIDE SEQUENCE OF 340-381.
RX   MEDLINE=91035620; PubMed=1699951; DOI=10.1083/jcb.111.5.2089;
RA   Small S.J., Akeson R.;
RT   "Expression of the unique NCAM VASE exon is independently regulated in
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RT   distinct tissues during development.";
RL   J. Cell Biol. 111:2089-2096(1990).
RN   [3]
RP   NUCLEOTIDE SEQUENCE [GENOMIC DNA] OF 355-364.
RX   MEDLINE=90166485; PubMed=2483093; DOI=10.1016/0896-6273(88)90158-4;
RA   Small S.J., Haines S.L., Akeson R.A.;
RT   "Polypeptide variation in an N-CAM extracellular immunoglobulin-like
RT   fold is developmentally regulated through alternative splicing.";
RL   Neuron 1:1007-1017(1988).
RN   [4]
RP   PROTEIN SEQUENCE OF 38-48 AND 594-605, AND MASS SPECTROMETRY.
RC   STRAIN=Sprague-Dawley; TISSUE=Brain;
RA   Lubec G., Kang S.U.;
RL   Submitted (JUL-2007) to UniProtKB.
CC   -!- FUNCTION: This protein is a cell adhesion molecule involved in
CC       neuron-neuron adhesion, neurite fasciculation, outgrowth of
CC       neurites, etc.
CC   -!- SUBCELLULAR LOCATION: Cell membrane; Single-pass type I membrane
CC       protein.
CC   -!- ALTERNATIVE PRODUCTS:
CC       Event=Alternative splicing; Named isoforms=1;
CC         Comment=A number of isoforms are produced;
CC       Name=1; Synonyms=N-CAM 140;
CC         IsoId=P13596-1; Sequence=Displayed;
CC   -!- SIMILARITY: Contains 2 fibronectin type-III domains.
CC   -!- SIMILARITY: Contains 5 Ig-like C2-type (immunoglobulin-like)
CC       domains.
CC   ----------------------------------------------------------------------
CC   Copyrighted by the UniProt Consortium, see http://www.uniprot.org/terms
CC   Distributed under the Creative Commons Attribution-NoDerivs License
CC   ----------------------------------------------------------------------
DR   EMBL; X06564; CAA29809.1; -; mRNA.
DR   EMBL; M32611; AAA41679.1; -; Genomic_DNA.
DR   PIR; S00846; IJRTNC.
DR   RefSeq; NP_113709.1; -.
DR   UniGene; Rn.11283; -.
DR   PDB; 1EPF; X-ray; 1.85 A; A/B/C/D=20-208.
DR   PDB; 1LWR; NMR; -; A=612-705.
DR   PDB; 1QZ1; X-ray; 2.00 A; A=20-308.
DR   PDBsum; 1EPF; -.
DR   PDBsum; 1LWR; -.
DR   PDBsum; 1QZ1; -.
DR   SMR; P13596; 509-609.
DR   Ensembl; ENSRNOG00000031890; Rattus norvegicus.
DR   GeneID; 24586; -.
DR   KEGG; rno:24586; -.
DR   RGD; 67378; Ncam1.
DR   HOVERGEN; P13596; -.
DR   LinkHub; P13596; -.
DR   NextBio; 603762; -.
DR   ArrayExpress; P13596; -.
DR   GermOnline; ENSRNOG00000031890; Rattus norvegicus.
DR   GO; GO:0016021; C:integral to membrane; IEA:UniProtKB-KW.
DR   GO; GO:0005886; C:plasma membrane; IEA:UniProtKB-KW.
```

```
DR   GO; GO:0008201; F:heparin binding; IEA:UniProtKB-KW.
DR   GO; GO:0005515; F:protein binding; IEA:UniProtKB-KW.
DR   GO; GO:0007155; P:cell adhesion; IEA:InterPro.
DR   InterPro; IPR008957; Fibronectin_typ-III-like_fold.
DR   InterPro; IPR003961; FN_III.
DR   InterPro; IPR013151; Ig.
DR   InterPro; IPR007110; Ig-like.
DR   InterPro; IPR013783; Ig-like_fold.
DR   InterPro; IPR013098; Ig_I-set.
DR   InterPro; IPR003598; Ig_sub2.
DR   InterPro; IPR009138; Neural_cell_adh.
DR   Gene3D; G3DSA:2.60.40.30; FN_III-like; 1.
DR   Gene3D; G3DSA:2.60.40.10; Ig-like_fold; 5.
DR   Pfam; PF00041; fn3; 2.
DR   Pfam; PF07679; I-set; 2.
DR   Pfam; PF00047; ig; 3.
DR   PRINTS; PR01838; NCAMFAMILY.
DR   SMART; SM00060; FN3; 2.
DR   SMART; SM00408; IGc2; 5.
DR   PROSITE; PS50853; FN3; 2.
DR   PROSITE; PS50835; IG_LIKE; 5.
PE   1: Evidence at protein level;
KW   3D-structure; Alternative splicing; Cell adhesion; Cell membrane;
KW   Direct protein sequencing; Glycoprotein; Heparin-binding;
KW   Immunoglobulin domain; Membrane; Phosphoprotein; Repeat; Signal;
KW   Transmembrane.
FT   SIGNAL        1     19       By similarity.
FT   CHAIN        20    858       Neural cell adhesion molecule 1.
FT                                 /FTId=PRO_0000015015.
FT   TOPO_DOM     20    721       Extracellular (Potential).
FT   TRANSMEM    722    739       Potential.
FT   TOPO_DOM    740    858       Cytoplasmic (Potential).
FT   DOMAIN       20    111       Ig-like C2-type 1.
FT   DOMAIN      116    205       Ig-like C2-type 2.
FT   DOMAIN      212    302       Ig-like C2-type 3.
FT   DOMAIN      309    414       Ig-like C2-type 4.
FT   DOMAIN      417    502       Ig-like C2-type 5.
FT   DOMAIN      507    606       Fibronectin type-III 1.
FT   DOMAIN      608    702       Fibronectin type-III 2.
FT   REGION      152    156       Heparin-binding (Potential).
FT   REGION      161    165       Heparin-binding (Potential).
FT   MOD_RES     784    784       Phosphoserine (By similarity).
FT   CARBOHYD    222    222       N-linked (GlcNAc. . .) (Potential).
FT   CARBOHYD    316    316       N-linked (GlcNAc. . .) (Potential).
FT   CARBOHYD    348    348       N-linked (GlcNAc. . .) (Potential).
FT   CARBOHYD    434    434       N-linked (GlcNAc. . .) (Potential).
FT   CARBOHYD    460    460       N-linked (GlcNAc. . .) (Potential).
FT   CARBOHYD    489    489       N-linked (GlcNAc. . .) (Potential).
FT   DISULFID     41     96       By similarity.
FT   DISULFID    139    189       By similarity.
FT   DISULFID    235    288       By similarity.
FT   DISULFID    330    396       By similarity.
FT   DISULFID    437    490       By similarity.
FT   STRAND       22     32
```

```
FT   STRAND       37     43
FT   STRAND       51     55
FT   STRAND       65     75
FT   STRAND       78     83
FT   HELIX        88     90
FT   STRAND       92     99
FT   STRAND      105    115
FT   STRAND      118    122
FT   STRAND      125    128
FT   STRAND      135    137
FT   STRAND      140    142
FT   STRAND      148    153
FT   HELIX       158    161
FT   STRAND      166    168
FT   STRAND      174    176
FT   HELIX       181    183
FT   STRAND      185    193
FT   HELIX       194    196
FT   STRAND      198    207
FT   STRAND      209    217
FT   STRAND      219    224
FT   STRAND      231    241
FT   STRAND      244    249
FT   STRAND      262    266
FT   STRAND      272    275
FT   HELIX       280    282
FT   STRAND      284    292
FT   STRAND      295    306
FT   STRAND      616    622
FT   TURN        623    626
FT   STRAND      627    633
FT   STRAND      637    639
FT   STRAND      642    654
FT   STRAND      667    673
FT   STRAND      679    688
FT   STRAND      691    701
SQ   SEQUENCE   858 AA;  94658 MW;  EA1A06A4EA0550F6 CRC64;

  Query Match             100.0%;  Score 76;  DB 1;  Length 858;
  Best Local Similarity   100.0%;  Pred. No. 0.00066;
  Matches   13;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 WFSPNGEKLSPNQ 13
              |||||||||||||
Db         54 WFSPNGEKLSPNQ 66
```

**SEQ ID NO: 2 (P13596 – Small et al.)**

```
Query Match             100.0%;  Score 76;  DB 1;  Length 858;
  Best Local Similarity   100.0%;  Pred. No. 0.00066;
  Matches   13;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 WFSPNGEKLSPNQ 13
              |||||||||||||
Db         54 WFSPNGEKLSPNQ 66
```

**SEQ ID NO: 4 (P13596 – Small et al.)**

```
Qy          1 QIRGIKKTD 9
              |||||||||
Db        175 QIRGIKKTD 183
```

**SEQ ID NO: 5 (P13596 – Small et al.)**

```
Qy          1 DVR 3
              |||
Db        162 DVR 164
```

**SEQ ID NO: 6 (P13596 – Small et al.)**

```
Qy          1 RGIKKTD 7
              |||||||
Db        178 RGIKKTD 183
```

**SEQ ID NO: 8 (P13596 – Small et al.)**

```
Qy          1 KEGED 5
              |||||
Db        130 KEGED 134
```

**SEQ ID NO: 9 (P13596 – Small et al.)**

```
Qy          1 IRGIKKTD 8
              ||||||||
Db        176 IRGIKKTD 183
```

**SEQ ID NO: 11 (P13596 – Small et al.)**

```
Qy          1 DKNDE 5
              |||||
Db        279 DKNDE 283
```

**SEQ ID NO: 12 (P13596 – Small et al.)**

```
Qy          1 TVQARNSIVNAT 12
              ||||||||||||
Db        213 TVQARNSIVNAT 224
```

**SEQ ID NO: 13 (P13596 – Small et al.)**

```
Qy          1 SIHLKVFAK 9
              |||||||||
Db        300 SIHLKVFAK 308
```

**SEQ ID NO: 14 (P13596– Small et al.)**

```
Qy          1 LSNNYLQIR 9
              |||||||||
Db        179 LSNNYLQIR 186
```

**SEQ ID NO: 15 (P13596 – Small et al.)**

```
Qy          1 RFIVLSNNYLQIR 13
              |||||||||||||
Db        175 RFIVLSNNYLQIR 186
```

**SEQ ID NO: 16 (P13596 – Small et al.)**

```
Qy          1 KKDVRFIVLSNNYLQIR 17
              |||||||||||||||||
Db        171 KKDVRFIVLSNNYLQIR 186
```

**SEQ ID NO: 17 (P13596 – Small et al.)**

```
Qy          1 QEFKEGEDAVIV 12
              ||||||||||||
Db        127 QEFKEGEDAVIV 138
```

**SEQ ID NO: 18 (P13596– Small et al.)**

```
Qy          1 KEGEDAVIVCD 11
              ||||||||||||
Db        130 KEGEDAVIVCD 140
```

***Response to Arguments***

15. Applicant's did not respond to the preceding rejection which was likely a mere oversight. However, given that the amendments to claim 8, part I, part (d) wherein the peptides *comprise* a peptide that is *50%* identical to those part I(a).

***Conclusion***

16. Claims 9,10,12,15,18-28 and 50-59 are objected to but would be allowable if rewritten in independent form. Claims are 8,13,14,16,17,41,44-49 and 60-65.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656
13 April 2010